

Attorney Docket No.: DRE-0067
Inventors: Laurencin et al.
Serial No.: 10/052,121
Filing Date: January 17, 2002
Page 4

RECEIVED
CENTRAL FAX CENTER
AUG 29 2006

REMARKS

Claims 1-3, 5 and 6 are pending in the instant application. Claims 1-3, 5 and 6 have been rejected. Claim 1 has been amended. Support for the amendment is provided in the specification in the paragraph bridging pages 8-9. No new matter is added by this amendment. Reconsideration is respectfully requested in light of this amendment and the following remarks.

I. Rejection of Claims 1-3, 5 and 6 under 35 U.S.C. 112, second paragraph

Claims 1-3, 5 and 6 have been rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner suggests that the phrase "several minutes" in line 5 of claim 1 is confusing and unclear. It is believed that the Examiner is referring to the phrase "several degrees" in claim 1 since the phrase "several minutes" is not used in claim 1. In an earnest effort to advance the prosecution of this case, Applicants have deleted the phrase "several degrees", instead amending the claim per the Examiner's suggestion to state "heating at a sintering temperature that is above the glass transition temperature of the polymer and below the melting temperature of the polymer".

Attorney Docket No.: DRE-0067
Inventors: Laurencin et al.
Serial No.: 10/052,121
Filing Date: January 17, 2002
Page 5

Support for this amendment is provided in teachings of the instant specification in the paragraph bridging pages 8-9.

Accordingly, no new matter is added by this amendment.

Withdrawal of this rejection under 35 U.S.C. 112, second paragraph is respectfully requested.

II. Rejection of Claims 1-3, 5 and 6 under 35 U.S.C. 103(a)

The rejection of claim 1 as being unpatentable over Starling et al. (U.S. Patent 6,210,715) in view of Crotts et al. has been maintained.

Claims 2, 3, 5 and 6 have also been rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 above, and further in view of Spaulding (U.S. Patent 6,001,643) or Granet et al. (Reference AJ of IDS).

Applicants respectfully traverse these rejections.

Amendments and arguments presented by Applicants in the last response were deemed unpersuasive. In particular, in response to Applicants' argument that Starling teach away from substituting with the microspheres of Crotts since the microspheres of Crotts et al. do not contain calcium phosphate, the Examiner suggests that "while Starling may prefer microspheres formed using calcium phosphate, this is not critical and Starling disclose that the microspheres can also be made of a polymer as an alternative to

Attorney Docket No.: DRE-0067
Inventors: Laurencin et al.
Serial No.: 10/052,121
Filing Date: January 17, 2002
Page 6

calcium phosphate". The Examiner relies upon teachings at col. 5 line 66 through col. 6, line 2 of Starling as supporting this suggestion. Further, the Examiner suggests that "coating with calcium as disclosed by Starling can be omitted when heating to soften the surface of a polymer as disclosed by Starling et al." The Examiner relies upon teachings at col. 6, lines 44-46, of Starling in support of this suggestion.

Applicants respectfully disagree with the Examiner's characterization of the teachings of Starling et al.

The passage of Starling at col. 5, line 66 through col. 6, line 2, suggested by the Examiner to disclose that the microspheres can also be made of a polymer as an alternative to calcium phosphate, actually reads as follows:

Porous CaP Coatings for Bonding to the Substrate Surfaces of Hollow or Solid Beads or Microbeads Comprised of CaP, Glass, Other Oxide Ceramics or Polymers, Proteinaceous Materials or Composite Materials (FIGS. 1, 1.1 and 1.3)

While CaP may not be required in the microspheres of this embodiment, this Section heading makes clear that CaP is in the coating of the microspheres. Thus, a scaffold of these coated microspheres does not consist of polymer microspheres as claimed in the instant application, but rather of microspheres and CaP.

Attorney Docket No.: DRE-0067
Inventors: Laurencin et al.
Serial No.: 10/052,121
Filing Date: January 17, 2002
Page 7

Further, contrary to the Examiner's suggestion, nowhere is it stated or even implied at col. 6, lines 44-46, of Starling that coating with calcium can be omitted when heating to soften the surface of a polymer. Lines 44-46 of col. 6 are under a section heading in Starling of "Porous CaP Coatings for Bonding to the Substrate Surfaces of Hollow or Solid Beads or Microbeads Comprised of CaP, Glass, Other Oxide Ceramics or Polymers, Proteinaceous Materials or Composite Materials (FIGS. 1, 1.1 and 1.3)". Further, the specific paragraph in which these lines are found begins with the sentence "Microbead substrate materials to be coated include, for example dense CaP, and other oxide ceramics" In addition, the sentence which precedes that cited by the Examiner states that "The CaP coating can be applied to porous substrates and then co-sintered to enhance bonding and further densify the substrate layers." Thus, contrary to the Examiner's suggestion, the implications of the teachings at col. 6, lines 44-46, when read in the context of the paragraph and Section in which the sentence resides in the patent application, are not that CaP coating is omitted but rather that "For polymeric and proteinaceous substrates, the preferred method for bonding" of the porous Cap coating "is reheating the substrate material"

Attorney Docket No.: DRE-0067
Inventors: Laurencin et al.
Serial No.: 10/052,121
Filing Date: January 17, 2002
Page 8

MPEP 2141.02 requires that a prior art reference be considered in its entirety, as a whole including portions that would lead away from the claimed invention. Also see *W.L. Gore & Associates, Inc. v. Garlock, Inc.* 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert denied, 469 U.S/ 851 (1984). The teachings of Starling et al., when read in their entirety and not as individual sentences extracted from their context, clearly lead away from the instant claimed invention, a scaffold for tissue engineering which does not contain CaP. Thus, this reference clearly lacks the requisite motivation or suggestion to make the claimed invention and fails to provide any reasonable expectation of success with respect to a tissue engineering scaffold which does not contain CaP.

Teachings of Crotts are unrelated to tissue engineering scaffolds, and teachings of Spaulding (U.S. Patent 6,001,643) or Granet et al. (Reference AJ of IDS) are merely cited for their teachings of cell culture techniques. Accordingly, these additional references fail to remedy deficiencies in the teachings of Starling et al.

MPEP 2144.04 II (B) states that omission of an element and retention of its functions is an indicia of unobviousness. Also see *In re Edge*, 359 F.2d 896, 149 USPQ 556 (CCPA 1966). Omission

Attorney Docket No.: DRE-0067
Inventors: Laurencin et al.
Serial No.: 10/052,121
Filing Date: January 17, 2002
Page 9

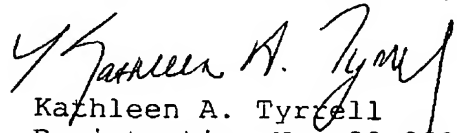
of CaP from the instant claimed tissue engineering scaffold while retaining the ability of the scaffold to exhibit cell attachment and retaining of cell phenotype upon in vitro culturing with cells in a rotating bioreactor as explicitly claimed is clearly indicative of the instant claimed invention being unobvious over the combination of cited prior art references.

Withdrawal of these rejections under 35 U.S.C. 103(a) is therefore respectfully requested.

III. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,


Kathleen A. Tyrrell
Registration No. 38,360

Date: August 29, 2006

Licata & Tyrrell P.C.
66 E. Main Street
Marlton, New Jersey 08053

856-810-1515